March 9, 2026

Perspectum, Ltd.
Bhaskar Chikkanna
Director of Quality Assurance and Regulatory Affairs
Gemini One, 5520 John Smith Dr.
Oxford, OX42LL
United Kingdom

Re: K253413
Trade/Device Name: LiverMultiScan (v6.0)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: March 5, 2026
Received: March 5, 2026

Dear Bhaskar Chikkanna:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253413

Please provide the device trade name(s).

LiverMultiScan (v6.0)

Please provide your Indications for Use below.

The device is indicated for use as a magnetic resonance diagnostic device software application for non-invasive assessment of liver health and the generation, display and review of magnetic resonance medical image data.

The device produces quantified metrics and composite images from magnetic resonance medical image data which, when interpreted by a trained healthcare professional, yield information on liver tissue characteristics that may assist in clinical decisions.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253413

Date Prepared: 11th December 2025

1 Applicant Details

Applicant Name and Address: Perspectum Ltd
Gemini One,
5520 John Smith Drive,
Oxford Business Park,
Oxford,
OX4 2LL

Owner/Operator Number: 10056574
Establishment Registration Number: 3014232555
Applicant Contact Name: Bhaskar Chikkanna
Applicant Contact Email: bhaskar.chikkanna@perspectum.com
Applicant Contact Phone: +44 (0) 1865 655343

2 Subject and Predicate Device

	Subject Device	Predicate Device
510(k) number	K253413	K213960
Legal Manufacturer	Perspectum Ltd.	Perspectum Ltd.
Device Trade Name	LiverMultiScan (v6.0)	LiverMultiScan (v5.0)
Common Name	Software as a Medical Device	Software as a Medical Device
Panel	Radiology	Radiology
Regulation	892.1000	892.1000
Risk Class	Class II	Class II
Product Class code	LNH	LNH
Regulation Name	Magnetic Resonance Diagnostic Device	Magnetic Resonance Diagnostic Device

3 Subject Device Description

3.1 General Description

LiverMultiScan is a standalone, post processing software as a medical device (SaMD). It enables the generation, display and review of magnetic resonance (MR) medical image data for non-invasive assessment of liver health based on imaging acquired during a single patient visit.

LiverMultiScan quantifies liver tissue characteristics from appropriately acquired MR datasets. It produces three quantitative metrics: iron-corrected T1 (cT1): which reflects fibro-inflammatory disease activity of the liver parenchyma, proton density fat fraction (PDFF): a measure of liver fat content, and liver iron concentration (LIC). Each of these metrics is standardized to a single reference, ensuring that reference ranges and clinical thresholds can be applied consistently, regardless of the MRI scanner used to acquire the measurement. cT1, PDFF and LIC all have a valid and well-founded correlation with liver histology and are associated with pathological processes such as fibro-inflammation, steatosis, and iron overload, respectively.

3.2 Indications for Use

The device is indicated for use as a magnetic resonance diagnostic device software application for non-invasive assessment of liver health and the generation, display and review of magnetic resonance medical image data.

The device produces quantified metrics and composite images from magnetic resonance medical image data which, when interpreted by a trained healthcare professional, yield information on liver tissue characteristics that may assist in clinical decisions.

3.3 Intended Patient Population

General population — LiverMultiScan has no demographic or population restrictions.

3.4 Contraindications

- None – Software only device

3.5 Warnings/Precautions

- The device output must be interpreted by trained healthcare professionals
- Very high liver iron concentration in excess of 5 mg Fe/g may give rise to inaccurate results
- Very high liver fat (PDFF > 30 %) may reduce the accuracy of cT1
- LIC above 3.0 mg Fe/g may reduce the accuracy of cT1
- LIC can be underestimated when above 3.5 mg Fe/g and liver fat content (PDFF) is between 10% and 25%.

4 Substantial Equivalence

Table below provides a comparison of attributes between the subject device and the predicate device to demonstrate substantial equivalence. Differences between the devices are commented.

Attributes	**Subject Device**	**Predicate Device**	**Comments**
Device trade name	LiverMultiScan v6.0	LiverMultiScan v5.0	N/A
Manufacturer	Perspectum Ltd	Perspectum Ltd	N/A
510(k) number (if assigned)	K253413	K213960	N/A
Regulation	892.1000	892.1000	No change
Product Code	LNH	LNH	No change
Indications for use	The device is indicated for use as a magnetic resonance diagnostic device software application for non-invasive assessment of liver health and the generation, display and review of magnetic resonance medical image data. The device produces quantified metrics and composite images from magnetic resonance medical image data which, when interpreted	LiverMultiScan v5 (LMSv5) is indicated for use as a magnetic resonance diagnostic device software application for non-invasive liver evaluation that enables the generation, display and review of 2D magnetic resonance medical image data and pixel maps for MR relaxation times. LMSv5 is designed to utilize DICOM 3.0 compliant magnetic resonance image datasets, acquired from compatible	Rephrased the indications for use for better readability without any change to its intent.

	by a trained healthcare professional, yield information on liver tissue characteristics that may assist in clinical decisions.	MR Systems, to display the internal structure of the abdomen including the liver. Other physical parameters derived from the images may also be produced. LMSv5 provides several tools, such as automated liver segmentation and region of interest (ROI) placements, to be used for the assessment of selected regions of an image. Quantitative assessment of selected regions includes the determination of triglyceride fat fraction in the liver (PDFF), T2*, LIC (Liver Iron Concentration) and iron corrected T1 (cT1) measurements. These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis.	
Intended users	• Perspectum trained analysts use the device to analyse MRI data and produce output. • Trained healthcare professionals interpret the device output for their clinical decision pathways.	• Perspectum trained analysts use the device to analyse MRI data and produce output. • Trained healthcare professionals interpret the device output for their clinical decision pathways.	No change
Anatomy and measurements	Liver Iron Corrected T1 (cT1) Proton Density Fat Fraction (PDFF) Liver Iron Concentration (LIC)	Liver Iron Corrected T1 (cT1) Proton Density Fat Fraction (PDFF) Liver Iron Concentration (LIC)	No change to the list of measurement output. However, the equation used to calculate the LIC value has changed in the subject device to align with the reference article. And, the cT1 calculation in the subject device is updated to account for T1 signal variations due to elevated fat in addition to what

			already existed in the predicate device.
Target population	General population	General population	No change
Contraindications	None, Software only	None, Software only	No change
Imaging modality	Magnetic resonance imaging systems	Magnetic resonance imaging systems	No change
Data format	DICOM 3.0 compliant MR image datasets from compatible MR scanners	DICOM 3.0 compliant MR image datasets from compatible MR scanners	No change
MRI Scanners	GE, Siemens and Philips	GE, Siemens and Philips	No change
MR field strength	1.5T and 3T	1.5T and 3T	No change
MR Acquisition Methods	NOLLI (Non-MOLLI) MOLLI MOST IDEAL	MOLLI MOST IDEAL	Subject device is modified to read MR scan data acquired through NOLLI (non-MOLLI) in additional to MOLLI method.

5 Software Testing

LiverMultiScan is a software medical device. The documentation level evaluation document justifies only basic documentation is applicable to LiverMultiScan as per FDA guidance, *Content of Premarket Submissions for Device Software Functions for Industry and Food and Drug Administration Staff Document issued on June 14, 2023.* The device has undergone the following tests and successfully passed the acceptance criteria with no residual anomalies.

a. Unit testing
b. Integration testing
c. Software system verification
d. Software system validation

6 Performance Testing

LiverMultiScan underwent performance testing under controlled conditions to corroborate that it is safe and effective when used as intended. The performance testing conducted demonstrates that the subject device is at least as safe and effective as the predicate device.

Scanners Assessed
Siemens 1.5T
Siemens 3T
GE 1.5T
GE 3T
Philips 1.5T
Philips 3T

The performance was tested for the following aspects:

a. Testing to reflect substantial equivalence for corrected T1 measurements between MOLLI and NOLLI
b. Repeatability of metrics for the same subject, on the same manufacturer and field strength, acquired on the same day
c. Reproducibility of metrics for the same subject, on the same manufacturer but a different field strength, acquired on the same day
d. Characterization of inter-operator variability
e. Characterization of intra-operator variability

f. Comparative testing between the operators' results and the gold standard (mean of 3 radiologists results)
g. Phantom data used for testing accuracy of measurements
h. In-vivo data used for tests a to f

All aspects of the performance tests met the defined acceptance criteria, thereby assuring robust clinical performance of the device across different scanners, field strengths and patient characteristics.

7 Conclusion

The subject device and the predicate device remain equivalent. The differences highlighted does not constitute a new intended use, are accompanied by information that demonstrates that the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate.